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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/008,179   | 12/07/2001  | William Ford         | 450117-03683        | 4143             |
| 20999  | 7590        | 09/02/2005           | EXAMINER            |                  |
| FROMMERM LAWRENCE & HAUG<br>745 FIFTH AVENUE- 10TH FL.<br>NEW YORK, NY 10151 |             |                      | MILLER, MARINA I    |                  |
|  |             | ART UNIT             | PAPER NUMBER        |                  |
|  |             | 1631                 |                     |                  |

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                           |                  |
|------------------------------|---------------------------|------------------|
| <b>Office Action Summary</b> | Application No.           | Applicant(s)     |
|                              | 10/008,179                | FORD ET AL.      |
|                              | Examiner<br>Marina Miller | Art Unit<br>1631 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 16 June 2005.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 2-9,31 and 32 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 2-9,31 and 32 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Applicants' submission filed on 6/16/2005 is acknowledged. Claims 2-9 and 31-32 are pending. Claims 1 and 10-30 are cancelled. Claims 2-9 and 31-32 presently are under examination.

Applicants' arguments have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are applied.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 5 recites the limitation "agents derived from." The recited limitation is vague and indefinite because the metes and bounds of what derivation includes (e.g., substitutions, deletions, additions, *etc.*) is not clear, and neither claims nor the specification define derivations. Technically, any agent may be derived from the recited agents. As the intended limitation is not clear, claim 5 is indefinite. Claim 6 depends from claim 5, and therefore indefinite.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 4-5, 7, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by

Dervan et al, U.S. Patent 5,998,140.

Dervan et al. disclose oligomers that fit into the minor groove of DNA molecule (col. 3, line 46 through col. 4, line 27) wherein terminus of the oligomers are used for linking detectable labels (nanoparticles) (e.g., colloidal gold particles (col. 7, lines 30-32)). Dervan et al. also disclose chelating groups comprising metal atoms (e.g., iron, cobalt, nickel, etc.) (col. 7, lines 36-40). Thus, Dervan et al. anticipate claim 2. Dervan et al. disclose pyrrole oligomers, thus anticipating claim 4 (col. 1, lines 43-47). Dervan et al. disclose that functional groups (e.g., nanoparticle binding groups) are bonded to a linker (an annular member) (col. 4, lines 56-60), thus anticipating claim 7. Dervan et al. disclose alkylating agents (e.g., sulfur mustards) (col. 7, lines 43-47), thus anticipating claim 5. Dervan et al. disclose light sensitive bond forming compounds, e.g., psoralen (col. 7, line 32), thus anticipating claim 32.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-4, 8-9, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maag et al, U.S. Patent 5,446,137.

Maag et al. disclose oligonucleotides comprising multiple (one, two, *etc.*) 4'-substituted nucleotides wherein the oligonucleotides hybridize to nucleic acids (*see abstract*) (col. 4, lines 12-39; col. 10, lines 13-18). 4'-substituted nucleotides may be modified to include DNA interacting groups (*e.g.*, DNA intercalators and minor groove binders) (col. 7, line 32, through col. 8, lines 9). The nucleotides may be also modified to include cleavage agents such as metal complexes (nanoparticles) (*e.g.*, platinum, iron, and copper complexes) (col. 8, lines 19-40). Maag et al. also disclose nucleotides comprising a suitable label for facilitating detection wherein the label may be a metal sol or metal ion (col. 9, lines 18-49). Thus, Maag et al. describe linker molecule species of instant claim 2. Maag et al. disclose that an intercalating molecule is represented by an acridine moiety, aromatic ligands, diazapyrenes, anthraquinones, *etc.* (col. 7, lines 56-64). Thus, Maag et al. describe species of instant claim 3. Maag et al. disclose groove-binding agents (*e.g.*, bis-benzimidazoles) (col. 8, lines 4-9), thus making obvious instant claim 4. Maag et al disclose that 4'-substituted nucleotides are introduced into oligonucleotides and the nucleotide modification groups (*e.g.*, nanoparticles mentioned above) are bound to the nucleotides by a linking group (*e.g.*, aminoalkyl, alkylether, etc.) (col. 9, lines 50-68), thus describing species of instant claims 8 and 9. Maag et al. teach a psoralen intercalating agent (col. 7, line 64), thus describing a specie of instant claim 32.

Species described within a generic disclosure are deemed suggested and motivated by such descriptions under 35 U.S.C. 103(a).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify a linker of Maag et al. to introduce an intercalating or groove-binding agent for binding nucleic acids and a nanoparticle binding site (cleavage agent or a label comprising a metal group), such as optionally taught as species by Maag et al., where the motivation would have been to improve interaction with DNA and to facilitate detection, as taught by Maag et al., (col. 7, lines 41-43; col. 8, lines 24-27; cols. 62-63).

Claims 5-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maag et al., U.S. Patent 5,446,137, as applied to claims 2-4, 8-9, and 32 above, in view of Houthoff et al., U.S. Patent 5,985,566.

Maag et al. make obvious the linker molecule of claims 2-4, 8-9, and 32, as set forth above.

Maag et al. do not disclose an alkylating agent, and specifically a metal coordination group.

Houthoff et al. disclose platinum-based linker compounds (coordination compounds comprising  $\text{Pt}^{2+}$  and  $\text{Pt}^{4+}$ ) used for labeling a biological target (*see abstract*). Houthoff et al disclose a metal complex comprising a ligand selected from halogens, nitrate, sulfate, carboxilate, etc. (col. 3, lines 35-47).

It would have been obvious to one skilled in the art at the time of the invention to modify a linker of Maag et al. to use an alkylating agent for binding nucleic acids, such as taught by Houthoff et al., where the motivation would have been to improve interaction with DNA, as taught by Houthoff et al., col. 1, lines 22-32.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Maag et al., U.S. Patent 5,446,137, as applied to claims 2-4, 8-9, and 32 above, in view of Barton, U.S. Patent 4,721,669.

Maag et al. make obvious the linker molecule of claims 2-4, 8-9, and 32, as set forth above.

Maag et al. do not disclose metallointercalator containing planar, aromatic ligands.

Barton discloses metallointercalator with planar heterocyclic residues (aromatic) (col. 1, line 35, through col. 4, line 19, and col. 7, lines 6-24).

It would have been obvious to one skilled in the art at the time of the invention to modify a linker of Maag et al. to use metallointercalators for binding nucleic acids, such as taught by Barton, where the motivation would have been to improve interaction with DNA and create new potential drug compounds, as taught by Barton, (col.2, lines 20-21).

### *Conclusion*

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D., can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller  
Examiner  
Art Unit 1631

MM

*Ardin H. Marschel 8/30/05*  
**ARDIN H. MARSCHEL**  
**SUPERVISORY PATENT EXAMINER**